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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,534	01/22/2002	Pradip Mukerji	6763.US.P1	3165

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STEVEN F. WEINSTOCK
ABBOTT LABORATORIES
100 ABBOTT PARK ROAD
DEPT. 377/AP6A
ABBOTT PARK, IL 60064-6008

EXAMINER	
SULLIVAN, DANIEL M	

ART UNIT	PAPER NUMBER
1636	15

DATE MAILED: 08/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/054,534	MUKERJI ET AL.	
	Examiner	Art Unit	
	Daniel M Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7 and 11-16, drawn to an isolated nucleic acid comprising a nucleic acid sequence selected from the group consisting of: SEQ ID NO: 13; SEQ ID NO: 19 or encoding SEQ ID NO: 20; SEQ ID NO: 28 or encoding SEQ ID NO: 29; SEQ ID NO: 30 or encoding SEQ ID NO: 31; SEQ ID NO: 32 or encoding SEQ ID NO: 33; SEQ ID NO 34 or encoding SEQ ID NO: 35, also directed to a vector and host cell comprising said nucleic acid, classified in class 536, subclass 23.1.

II. Claims 8 and 9, drawn to a purified polypeptide selected from the group consisting of: comprising SEQ ID NO: 14 or encoded by SEQ ID NO: 13; SEQ ID NO: 20 or encoded by SEQ ID NO: 19; SEQ ID NO: 29 or encoded by SEQ ID NO: 28; SEQ ID NO: 31 or encoded by SEQ ID NO: 30; SEQ ID NO: 33 or encoded by SEQ ID NO: 32, classified in class 435, subclass 189.

III. Claims 15, 16 and 18, drawn to a transgenic plant comprising the nucleic acid of claim I and the polypeptide of claim II, classified in class 800, subclass 295.

IV. Claim 17, drawn to a plant oil or acid expressed by the plant of Group III, classified in class 532, subclass 1.

V. Claims 19-24, drawn to a method for producing a polyunsaturated fatty acid using a nucleic acid of Group I selected from a nucleic acid comprising SEQ ID NO: 19, SEQ ID NO: 28, SEQ ID NO: 30 or SEQ ID NO: 34, classified in class 532, subclass 1.

VI. Claims 25-30, drawn to a method for producing a polyunsaturated fatty acid using a nucleic acid of Group I selected from a nucleic acid comprising SEQ ID NO: 13 or SEQ ID NO: 32, classified in class 532, subclass 1.

VII. Claims 31-34, drawn to a composition comprising at least one polyunsaturated fatty acid produced according to the method of claims 19, 21 or 23, classified in class 532, subclass 1.

VIII. Claims 31-34, drawn to a composition comprising at least one polyunsaturated fatty acid produced according to the method of claims 25, 27 or 29, classified in class 532, subclass 1.

IX. Claim 35, drawn to a method of preventing or treating a condition in a patient comprising administering the composition of Group VII, classified in class 532, subclass 1.

X. Claim 35, drawn to a method of preventing or treating a condition in a patient comprising administering the composition of Group VIII, classified in class 532, subclass 1.

The inventions are distinct, each from the other because of the following reasons:

The nucleic acids of Invention I are related to the protein of Invention II by virtue of encoding the same. The DNA molecule has utility for the recombinant production of the protein in host cells. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the

natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The protein of Invention II and nucleic acid of Invention I are related to the transgenic plant of Invention III in that the plant can be produced using the nucleic acid of Invention I and comprises the protein of Invention II. The plant is distinct from the protein and nucleic acid, however, because they are physically and functionally distinct and the peptide and nucleic acid can be used for processes other than production of the transgenic plant, such as to raise antibodies, or screen for agents that bind to the protein or nucleic acid. Furthermore, patentability of the transgenic plant arises from the phenotypic characteristics of the plant; thus, patentability of the transgenic plant is not solely dependent upon the particulars of the nucleic acid or polypeptide comprised within the plant.

The protein of Invention II, nucleic acid of Invention I and transgenic plant of Invention III are related to the plant oil of Invention IV in that the protein and nucleic acid are comprised within the plant or cell used to produce the oil, and the oil is produced by the plant cell or plant. However, each of the inventions are directed to distinct physical, chemical and functional entities. Further, as the plant oil or acid of Group IV is not limited to an oil or acid that is uniquely produced by the genetically engineered plant, the oil or acid could be produced by a materially different plant such as the wild type plant or cell from which the engineered plant or cell is established.

Likewise, the products of Inventions I-IV and the methods of Inventions V and VI are related to the products of Inventions VII and VIII in that the products of Inventions I-IV can be used in the methods of Inventions V and VI to produce the polyunsaturated fatty acids of

Inventions VII and VIII. However, the polyunsaturated fatty acids can be made by a materially different process such as chemical synthesis or using a purified enzyme *in vitro*.

The products of Inventions I and II are related to the methods of Inventions V and VI in that the products can be used in the methods. However, each of the products can be used in a materially different process such as to raise antibodies, or screen for agents that bind to the protein or nucleic acid. The transgenic plant of Invention III is unrelated to the methods of Inventions V and VI because the methods are not limited to making or using the plant of Invention III.

The product of Invention IV is related the processes of Inventions V and VI in that the plant oil could be made according to the processes of Inventions V or VI. However, as the plant oil or acid of Group IV is not limited to an oil or acid that is uniquely produced by the methods as claimed, the oil or acid could be produced by a materially different method such as extraction from a wild type plant or cell.

The methods of Inventions V and VI are distinct in that the method of Invention V is directed to a method of producing a polyunsaturated fatty acid using a Δ5 desaturase and the method of Invention VI is directed to a method of producing a polyunsaturated fatty acid using a Δ6 desaturase. The methods are not disclosed as capable of use together in a single process and, as the products used in and made by the methods are distinct, the methods have distinct modes of operation, function and effect.

The methods of Inventions IX and X are related to the products and methods of Inventions I-VIII in that the products of Inventions VII and VIII can be used in the methods of

Inventions IX and X. However, the products can be used in a materially different process such as for cosmetic purposes as set forth in the third full paragraph on page 44.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, or because each of the distinct Inventions comprise distinct elements and therefore cannot be searched coextensively, restriction for examination purposes as indicated is proper.

Finally, each polypeptide and nucleic acid sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because the protein encoded by these sequences differs in structure and in function. A restriction is applied to each Group insofar as it encompasses a unique nucleic acid or protein. For an elected Group drawn to a nucleotide sequence, the Applicants must elect a single nucleic acid sequence "X", a single nucleic acid encoding a polypeptide "Y" and a single cDNA contained in clone "Z" (See MPEP 803.04).

The search of the selected sequence may include the complements of the selected sequences and, where appropriate, may include subsequences within the selected sequences (e.g., oligomeric probes and/or primers).

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. Similarly, proteins comprising unique amino acid sequences are structurally and functionally distinct. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide and amino acid sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms
August 8, 2003

Anne-marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER